REMARKS

Claims 1-3, 7-10, 66-68 and 72-75 are pending in the application.

Claims 1-3, 7-10, 66-68 and 72-75 stand rejected.

Applicant amends claims 1, 2, 3, 7, 66, 67, 68 and 72 and adds new claims 76-81.

Applicant's amendment to recite "stop member" in place of "ring" is support in the specification it at least paragraphs [0023, 0059, 0073, and 0082]. "The catheter includes a tubular body, at least one elongate member and a **stop** . . and the proximal end of the elongate member is attached to the **stop**. The **stop** being slidable along the tubular body." [0023] (emphasis added). "The catheter 26 has a **pulling means 28 (e.g., ring member, stop, or stopping device) . . . in the form of a ring or ring member that is slidingly attached on the catheter tubing 30**. [0059] (emphasis added).

Applicant's pending claims are generally directed to a catheter configured to form a position **locking loop** at the end thereof automatically in response to insertion of the catheter. This is accomplished by interaction of a catheter stop member with the skin of the patient, an introducer hub or other adjacent obstacle as the catheter is inserted and advanced beyond the length of an elongated tensile member extending between the stop member and the end of the catheter to pull the catheter end into a loop. In the context of insertion into a body cavity, once the stop member is abutting the skin of the patient, continued insertion causes the stop member to pull the catheter end into a loop. In the context of insertion using an introducer, once the stop member is abutting the introducer, continued insertion causes the stop member to pull the catheter end into a loop. "In general, **steps (5) and (6) [of loop formation] are automatically performed by virtue of the pulling thread 32 being attached to the ring 28, which functions as a stopping means** when it abuts the hub 25b of the introducer." [0073] (emphasis added). Thus, the claimed invention provides **automatic** formation of the loop upon insertion of the catheter, without the need for additional manipulation by the practitioner.

Figs. 4a-4d and the corresponding detailed description in paragraphs [0073-0077] are illustrative of the loop formation feature of the claimed invention. It may also be helpful to note that just prior to the loop formation stage shown in Fig. 4a, stop member 28 is not yet in contact with connector 25b. Initial insertion of the catheter causes stop member 28 to abut against connector 25b, at which point continued insertion causes stop member 28 to slide along the catheter (or the catheter through the stop member) to begin the loop formation stages depicted in Figs. 4a-4d.

Claim Rejections – 35 U.S.C. § 103

Claims 1-3, 8-10, 66-68 and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/04724 to Brennen et al. ("Brennen") in view of U.S. Pat. Pub. No. 2001/0044625 to Hata et al. ("Hata"). Claims 7 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan in view of Hata as applied to claims 1-3, 8-10, 66-68 and 73-75 above, and further in view of U.S. Pat. No. 4,906,230 to Maloney et al. ("Maloney"). Applicant respectfully traverses these rejections as set forth in the following remarks and asserts that both the problems and the solutions addressed by the these references are entirely different from those addressed by Applicant's claimed invention.

The Brennen, Hata and Maloney references address the problem of steering a catheter with different manual steering devices. In particular, the Brennen reference is directed to a "steerable stylet" in which a pull wire is operated by manipulation of a handle to "guide" a tubular member. (Abstract). The Hata reference is directed to a "steerable ablation catheter comprising . . . a movable electrode on a deployable wire loop assembly" for delivering an electrical shock to a target tissue. (Field of the Invention, Abstract). The Hata reference discloses "a steering mechanism at the handle for controlling deflection of the catheter distal section." (paragraph [0022]). Similarly, the Maloney reference is directed to "a steerable, e.g., maneuverable, catheter" having a "bellows located at or near the distal end of the catheter [which] can be controllably deflected . . . to easily maneuver the catheter through the tortuous path." (Col. 1, lines 52-53, Abstract).

Brennan explains that the curvature at the tip of such catheters is achieved by manual steering and pulling by the practitioner of the stylet's manipulation handle to follow e.g. the curvatures during advancement through a blood vessel. Brennen employs a two-piece catheter having a steerable stylet with a hollow tube and a separate manipulative handle assembly for temporarily engaging an elongate member, e.g., pull wire. In contrast, the claimed invention is directed to an integral drainage catheter in which the "pull-wire" or elongate member is fixedly connected to the stop member. Because the manipulative steering handle of Brennan is used only during the "steering" phase of insertion, one of ordinary skilled in the art would not look to fixedly attached the pull wire to such a handle.

Each of the cited references is expressly directed towards **steering** a catheter along a curved or tortuous path. In each of these references, the steering of the curvature at the tip of the catheter is achieved by manipulation of a handle by the practitioner's hands to form a curve. As is clearly described by Brennen on page 8, lines 25-26, a dynamic curvature of between 0 and 180 degrees may be introduced to the catheter tip. Applicant notes that such curves do not constitute a loop.

In contrast, as stated above, applicants' pending claims are directed to a loop locking catheter having a stop member and an elongated member connected to both the catheter end and the stop member. Accordingly, neither Brennen, Hata, Maloney nor any combination thereof teach or suggest a loop formed at the end of a catheter let alone a catheter "configured such that inserting the tubular catheter body causes the stop member to pull the elongate member to form a loop in the distal region of the tubular catheter body" as recited in amended independent claim 1. Similarly, neither Brennen, Hata, Maloney nor any combination thereof teach of suggest a catheter "configured such that sliding of the first elongate member relative to the protruding member pulls the second elongate member to form a loop in the distal region of the first elongate member" as recited in amended independent claim 66.

Without such a disclosure, none of the proposed combinations of references support a *prima facie* case of obviousness. Even if one ordinary skill in the art were in possession of the Brennen, Hata and Maloney steerable catheter references, such a person would not consider

changing such steerable catheters to have the claimed connected stop member and elongated member for automatically forming a loop because such a loop would render the Brennen, Hata and Maloney devices useless for their intended purposes. In particular, formation of a loop at the catheter end as claimed by applicant would greatly hinder or preclude steering through a blood vessel.

Accordingly, Applicant submits that claims 1 and 66 are allowable over the cited references and that the various dependent claims and new claims 76-81 are likewise allowable as dependent upon claims 1 or 66. Applicant therefore requests that the corresponding rejections be withdrawn.

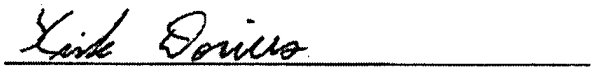
CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reason for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to amendment.

Applicant requests a two month extension as indicated in the accompanying petition for a extension of time. All fees are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply all charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 12389-004001.

Respectfully submitted,

Date: January 2, 2008



Kirk Dorius
Reg. No. 54,073

Fish & Richardson P.C.
One Congress Plaza, Suite 810
111 Congress Avenue
Austin, TX 78701
Telephone: (512) 472-5070
Facsimile: (512) 320-8935